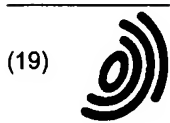


10/616,887



(19)

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 096 884 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
29.03.2006 Bulletin 2006/13

(51) Int Cl.:
A61B 17/04 (2006.01)

(21) Application number: **99929684.1**

(86) International application number:
PCT/IL1999/000384

(22) Date of filing: **13.07.1999**

(87) International publication number:
WO 2000/002488 (20.01.2000 Gazette 2000/03)

(54) APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION

GERÄT ZUR HÄMOSTASE NACH ARTERIELLER KATHETERISIERUNG

APPAREIL POUR L'HEMOSTASE APRES UNE CATHETERISATION ARTERIELLE

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**

(72) Inventor: **Barak, Shlomo**
Rishon le Zion 75258 (IL)

(30) Priority: **13.07.1998 US 114817**

(74) Representative: **Elzaburu Marquez, Alberto et al**
Elzaburu S.A.
Miguel Angel, 21
28010 Madrid (ES)

(43) Date of publication of application:
09.05.2001 Bulletin 2001/19

(73) Proprietor: **Cardiodex Ltd.**
Tirat HaCarmel 39120 (IL)

(56) References cited:
US-A- 5 486 195 **US-A- 5 540 715**
US-A- 5 645 566 **US-A- 5 728 134**

EP 1 096 884 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to apparatus for hemostasis following arterial catheterization.

[0002] Various techniques are known for arterial catheterization. Following arterial catheterization, it is necessary to cause hemostasis quickly and without undue hardship for the patient.

[0003] Applicant's U.S. Patent 5,728,134 and Published PCT Patent application WO 98/11830 describe a method and apparatus for hemostasis which greatly simplifies hemostasis and thus greatly reduces patient discomfort following arterial catheterization. The prior art referenced in Applicant's Published PCT Patent application WO 98/11830 and U.S. Patent 5,728,134 is considered to represent the state of the art.

[0004] US 5,486,195 discloses an apparatus for sealing an arteriotomy site in a patient, comprising a first catheter to be introduced in the artery, a second catheter through which the first catheter may be introduced, both catheters having respective distal balloons to be inflated, and means to deliver a material to seal the arteriotomy site. The hemostatic material is finally injected through a small hole near the forward end of the catheter.

SUMMARY OF THE INVENTION

[0005] The present invention seeks to provide improved apparatus for hemostasis.

[0006] There is provided in accordance with the present invention apparatus for hemostasis of an artery having a puncture after arterial catheterization as in claim 1.

[0007] Additionally in accordance with a preferred embodiment of the present invention, the apparatus additionally includes an injector for injecting a hemostatic agent via the catheter introducer to a location external of the artery.

[0008] Preferably, the forward edge of the catheter introducer extends less than 4 mm beyond the forward edge of the balloon when not inflated.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

[0010] Figs. 1 - 12 are simplified illustrations of apparatus for hemostasis following arterial catheterization, in accordance with the present invention employing a novel catheter, and its method of use wherein:

Fig. 1 is an illustration of insertion of a catheter introducer into an artery as known in the prior art;

Fig. 2 is an illustration of the catheter introducer and an associated catheter during arterial catheterization as known in the prior art;

Fig. 3 is an illustration of the catheter introducer fol-

lowing removal of the catheter used during arterial catheterization as known in the prior art;

Fig. 4 is an illustration of introduction of a hemostasis catheter into the artery;

Fig. 5 is an illustration of inflation of an inflatable anchor in hemostasis catheter;

Fig. 6 is an illustration of retraction of the hemostasis catheter into engagement with the forward end of the catheter introducer;

Fig. 7 is an illustration of retraction of the hemostasis catheter such that the inflated inflatable anchor lies against an inner wall surface of a wall of the artery; Fig. 8 is an illustration of retraction of the catheter introducer from the vicinity of the artery;

Fig. 9 is an illustration of partial inflation of a balloon adjacent the forward end of the hemostasis catheter such that blood flow out of the artery is prevented by the inflated balloon;

Fig. 10 is an illustration of deflation of the inflatable anchor following the step of Fig. 9;

Fig. 11 is an illustration of further inflation of the balloon adjacent the forward end of the hemostasis catheter such that the forward end of the hemostasis catheter is retracted and spaced from an outer wall surface of the wall of the artery and blood flow out of the artery is prevented by the inflated balloon; and Fig. 12 is an illustration of injection of a hemostatic agent following the step illustrated in Fig. 11.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0011] Reference is now made to Figs. 1 - 12, which are simplified illustrations of apparatus for hemostasis following arterial catheterization, in accordance with the present invention employing a novel hemostasis catheter, and of its use.

[0012] The method and apparatus of Figs. 1 - 12 employs a conventional catheter introducer 110 having a forward end 111, which is introduced into an artery 112 in an entirely conventional manner, as well known in the prior art, and shown in Fig. 1. Arterial catheterization is also carried out in an entirely conventional manner using a conventional catheter 114, as shown in Fig. 2. Following removal of the catheter 114, the conventional catheter introducer 110 remains in the artery 112 as illustrated in Fig. 3 and well known in the prior art.

[0013] At this stage, as shown in Fig. 4, a hemostasis catheter 120, constructed and operative in accordance with the present invention, is introduced into the artery 112 via the catheter introducer 110. The hemostasis catheter 120 comprises a sheath 122 having first and second lumens 123 and 124 having a pair of heads 125 and 126, associated with respective valves 128 and 130. Adjacent a forward end 131 thereof, there is provided a peripheral balloon 132 and extending forwardly of the forward end 131 there is provided an anchor balloon 134.

[0014] Following introduction of the hemostasis cath-

eter 120, the anchor balloon 134 is inflated within artery 112 as illustrated in Fig. 5, typically by means of a syringe 140 coupled via valve 128, head 125 and lumen 123.

[0015] Following inflation of the anchor balloon 134, the entire hemostasis catheter 120 is preferably retracted such that the inflated anchor balloon 134 abuts against the forward end 111 of the catheter introducer 110, as seen in Fig. 6.

[0016] The hemostasis catheter 120 is further retracted, as shown in Fig. 7, thus also retracting the catheter introducer 110 due to the engagement of the inflated anchor balloon 134 against the forward end 111 of the catheter introducer 110. This retraction preferably proceeds until the inflated anchor balloon 134 lies against an inner wall surface 160 of a wall 162 of the artery 112. In this orientation, inflated anchor balloon 134 prevents blood flow through aperture 166 in wall 162.

[0017] As seen in Fig. 8, the catheter introducer 110 is slightly retracted, as indicated by arrow 164, sufficient to allow peripheral balloon 132 to be inflated, and to bring the forward end 110 of the catheter introducer out of engagement with the artery wall 162, while retaining the forward end 110 within the tissue and in the general vicinity of the aperture 166 in the artery wall 162.

[0018] Following the retraction of the catheter introducer 110 illustrated in Fig. 8, the peripheral balloon 132 is partially inflated, as illustrated in Fig. 9. This inflation is preferably effected by means of a syringe 170 coupled via valve 130, head 126 and lumen 124. The partial inflation is preferably such that blood flow out of the artery is prevented by the inflated balloon 132.

[0019] Following the partial inflation illustrated in Fig. 9, the anchor balloon 134 is deflated, as shown in Fig. 10. Following deflation of the anchor balloon 134, the peripheral balloon 132 is further inflated such that the forward end 131 of the hemostasis catheter is retracted and spaced from an outer wall surface of the wall of the artery and blood flow out of the artery is prevented by the inflated balloon 132.

[0020] It is a particular feature of the present invention that the placement of peripheral balloon 132 relative to the forward end 131 of the hemostasis catheter is such that when the balloon 132 is fully inflated, as shown in Fig. 11, the forward facing outer surface 168 of the balloon 132 lies forward of the forward end 131 of the hemostasis catheter 120 and thus, due to engagement of the surface 168 with an outer wall surface 170 of artery 112, retracts the forward end 131 of the hemostasis catheter out of engagement with the wall 162 of artery 112, while the outer wall surface 170 of the artery is at the same time tightly engaged by forward facing outer surface 168 of balloon 132.

[0021] The resulting sealing arrangement enables hemostasis to occur at the aperture 164 formed in wall 162 of artery 112. Following sufficient hemostasis the peripheral balloon 132 is deflated and the hemostasis catheter 120 is removed.

[0022] Optionally, as illustrated in Fig. 12, a hemostatic

agent 176 may be injected via the catheter introducer 110 to a location adjacent aperture 174 but outside the artery 112. This injection may employ a syringe 178 which may be coupled via pressure gauge 118.

Claims

1. Apparatus for haemostasis of an artery (112) having a puncture after arterial catheterisation, the apparatus comprising:

a haemostasis catheter (120) including an inflatable anchor (134) at a forward end thereof and a balloon (132) adjacent said forward end and spaced from said inflatable anchor;
a selectable inflator for inflating the inflatable anchor inside said artery;
wherein the forward edge of the haemostasis catheter extends forwardly less than the extent of the balloon when inflated, whereby inflation of the balloon (132) adjacent the forward end of the haemostasis catheter in engagement with the outer wall surface of the artery causes the forward end of the haemostasis catheter to be withdrawn completely from the wall of the artery and to be spaced therefrom.

2. Apparatus for hemostasis of an artery according to any of the preceding claims and also comprising an injector for injecting a hemostatic agent to a location external of the artery.

3. Apparatus for hemostasis according to any of the preceding claims and wherein said forward end extends less than 4 mm beyond a forward edge of the balloon when not inflated.

Patentansprüche

1. Vorrichtung zur Blutstillung einer Arterie (112), die nach einer arteriellen Katheterisierung einen Einstich aufweist, wobei die Vorrichtung umfasst:

einen Blutstillungskatheter (120), der einen aufpumpbaren Anker (134) an seinem vorderen Ende und einen Ballon (132) benachbart zum vorderen Ende und im Abstand vom aufpumpbaren Anker aufweist;
eine wählbare Aufpumpereinrichtung zum Aufpumpen des aufpumpbaren Ankers innerhalb der Arterie;
bei welcher sich der vordere Rand des Blutstillungskatheters weniger weit nach vorne erstreckt als die Erstreckung des Ballons, wenn er aufgepumpt ist, wodurch ein Aufpumpen des Ballons (132) benachbart zum vorderen Ende

des Blutstillungskatheters im Eingriff mit der äußeren Wandoberfläche der Arterie bewirkt, dass das vordere Ende des Blutstillungskatheters vollständig aus der Wand der Arterie herausgezogen wird und im Abstand von dieser angeordnet ist. 5

2. Vorrichtung zur Blutstillung einer Arterie nach einem der vorangehenden Ansprüche und auch umfassend einen Injektor zum Injizieren eines blutstillenden Mittels zu einer Stelle außerhalb der Arterie. 10
3. Vorrichtung zur Blutstillung einer Arterie nach einem der vorangehenden Ansprüche und bei der sich das vordere Ende weniger als 4 mm über einen vorderen Rand des Ballons hinaus erstreckt, wenn er nicht aufgepumpt ist. 15

Revendications 20

1. Dispositif pour une hémostase d'une artère (112) présentant une perforation après une cathétérisation artérielle, le dispositif comprenant : 25

un cathéter d'hémostase (120) comprenant une ancre gonflable (134) à son extrémité avant et un ballonnet (132) adjacent à ladite extrémité avant et espacé de ladite ancre gonflable, un gonfleur pouvant être choisi destiné à gonfler l'ancre gonflable à l'intérieur de ladite artère, où le bord avant du cathéter d'hémostase s'étend moins vers l'avant que l'étendue du ballonnet lorsqu'il est gonflé, grâce à quoi le gonflement du ballonnet (132) adjacent à l'extrémité avant du cathéter d'hémostase en contact avec la surface de paroi extérieure de l'artère amène l'extrémité avant du cathéter d'hémostase à être complètement retirée de la paroi de l'artère et à en être espacée. 30 35 40
2. Dispositif pour une hémostase d'une artère selon la revendication 1, et comprenant également un injecteur destiné à injecter un agent hémostatique sur un emplacement externe à l'artère. 45
3. Dispositif pour une hémostase selon l'une quelconque des revendications précédentes, et dans lequel ladite extrémité avant s'étend sur moins de 4 mm au-delà d'un bord avant du ballonnet lorsqu'il n'est pas gonflé. 50

55

FIG. 1
(PRIOR ART)

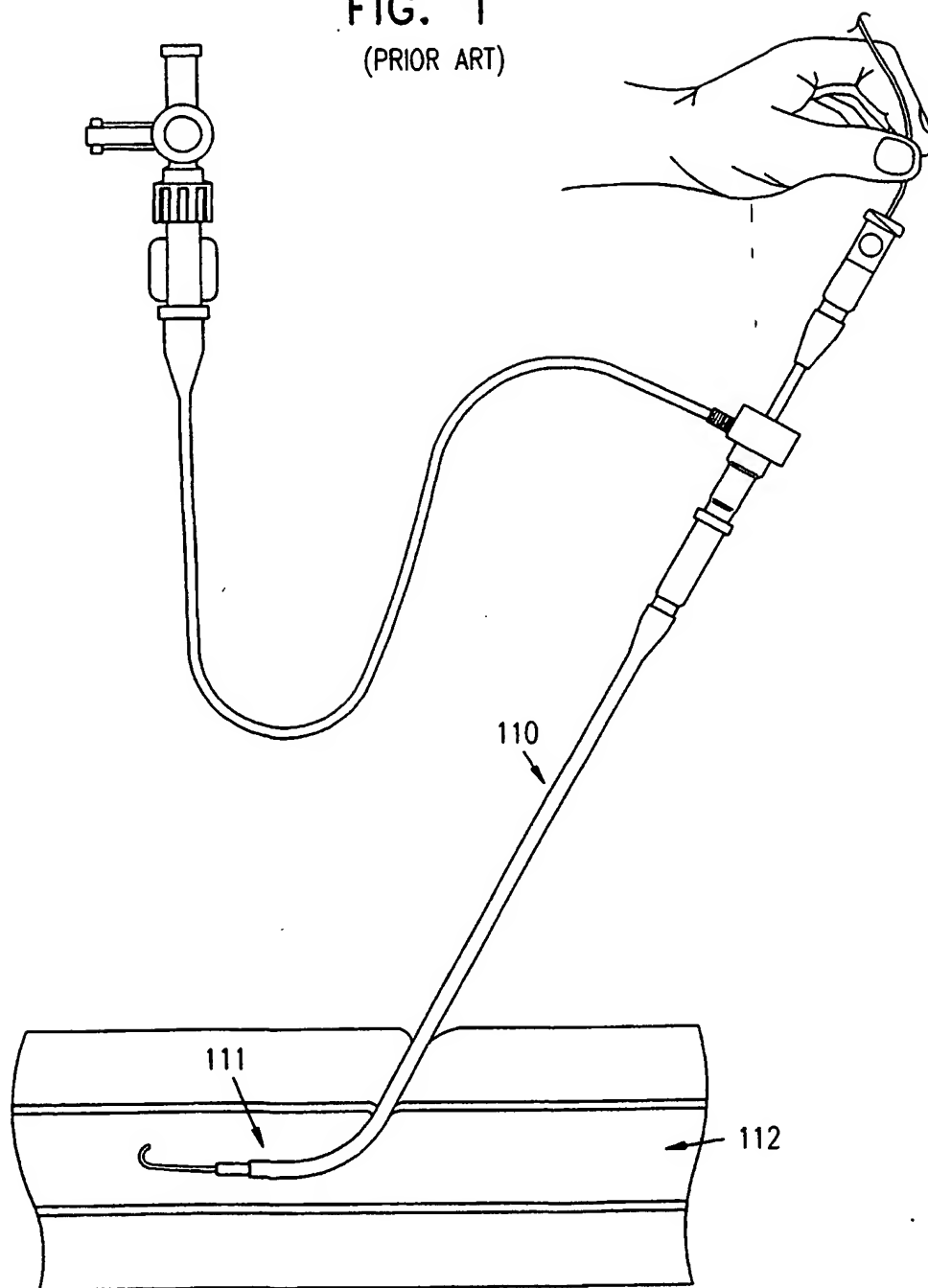


FIG. 2
(PRIOR ART)

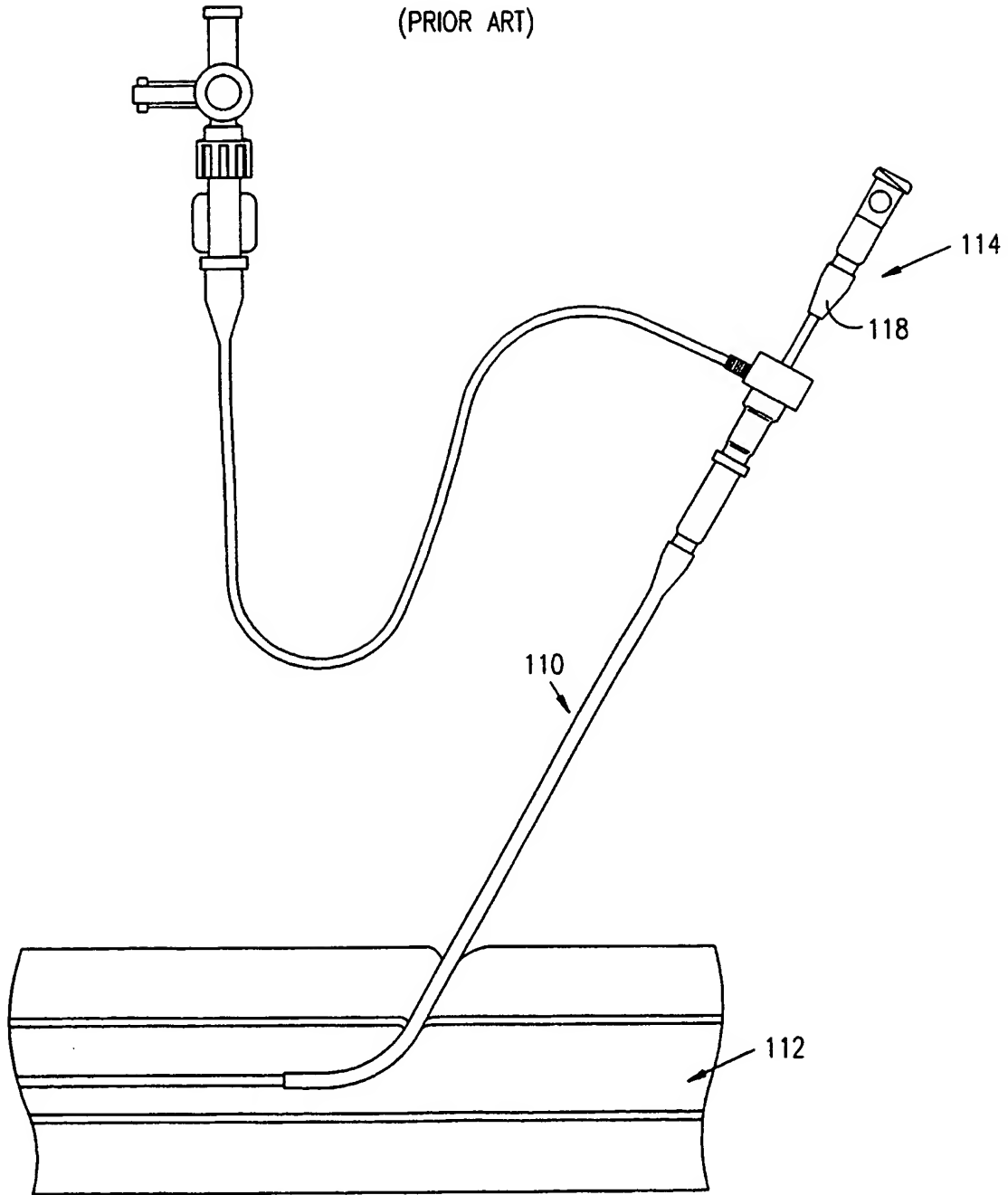


FIG. 3
(PRIOR ART)

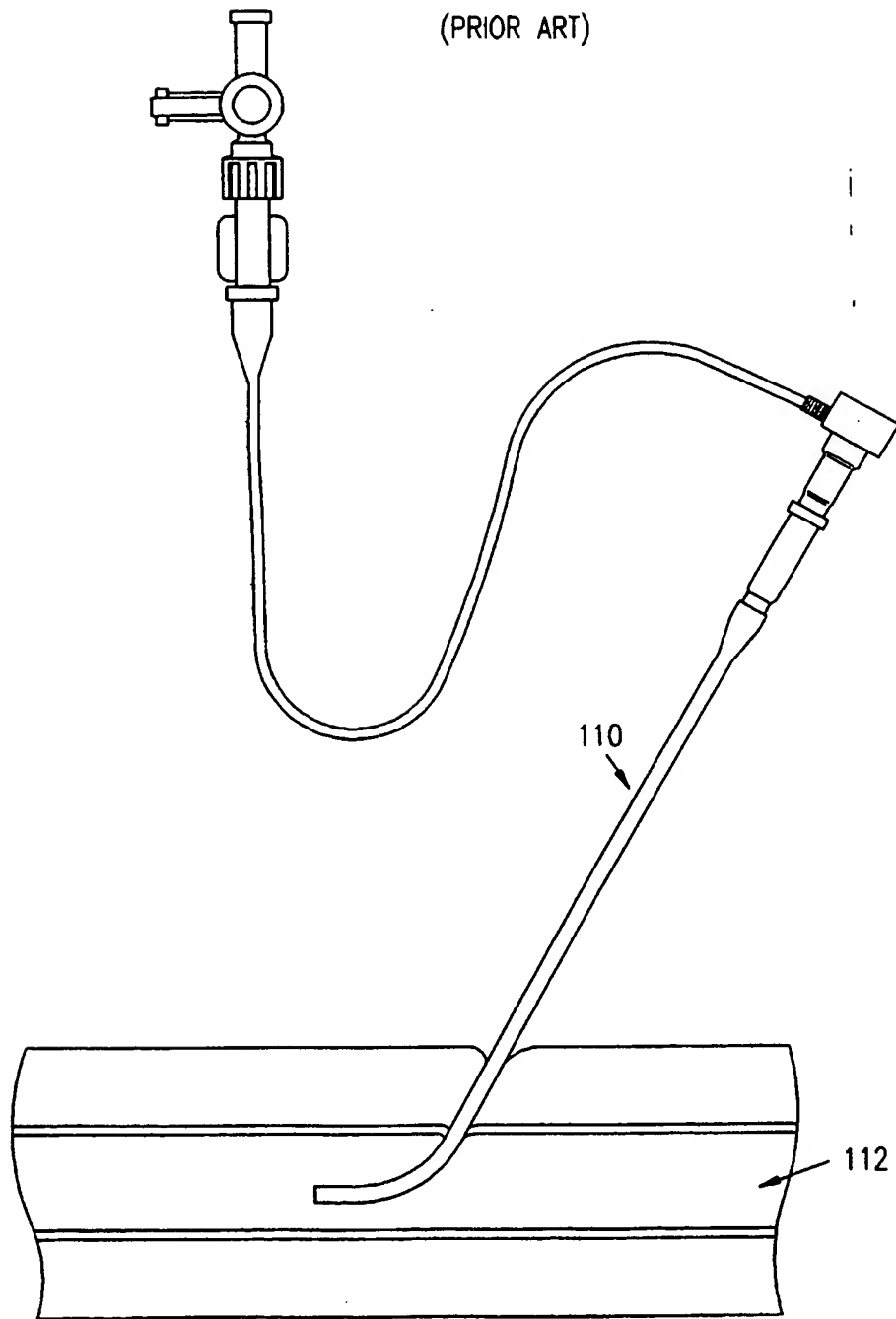


FIG. 4

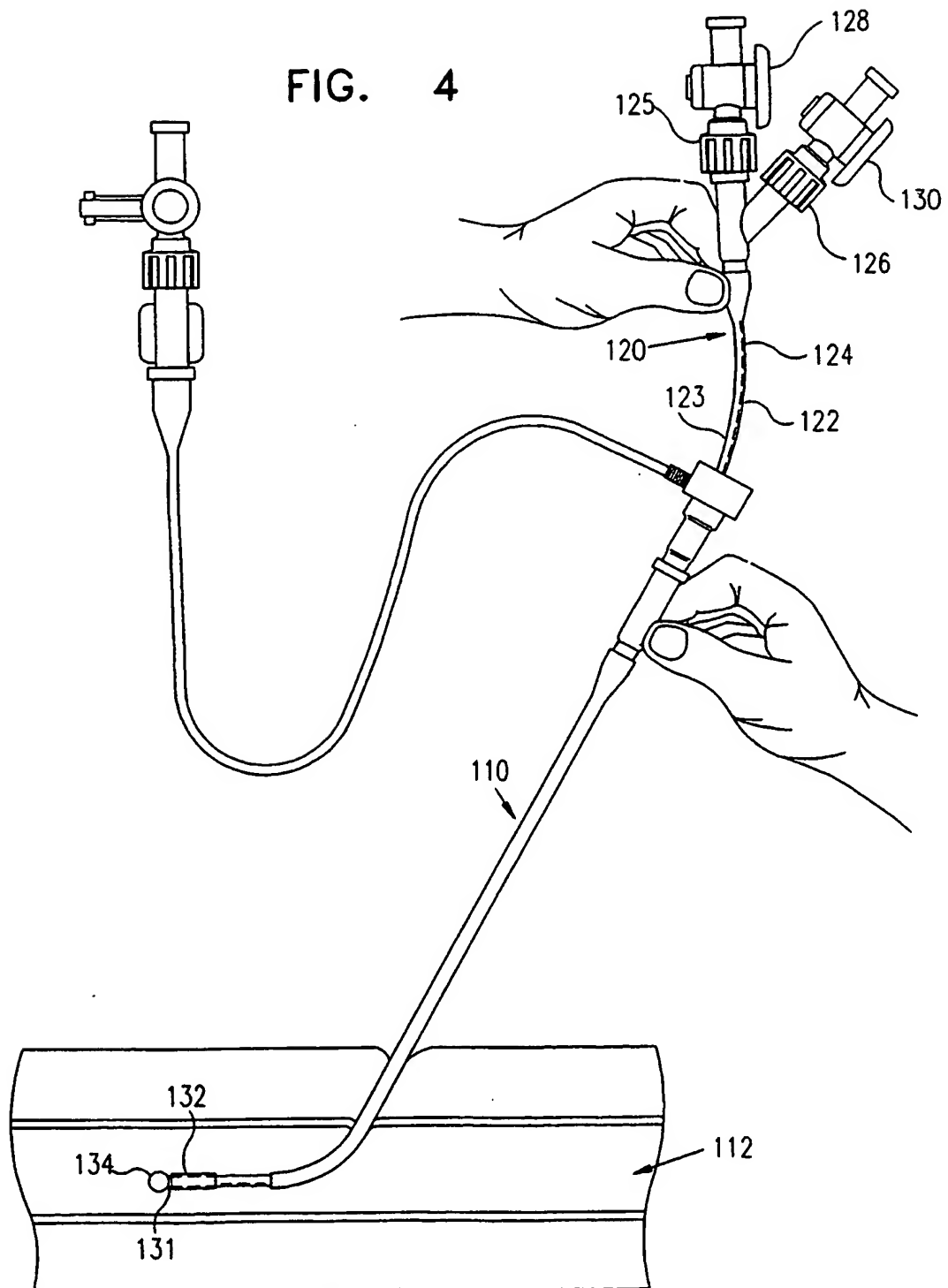


FIG. 5

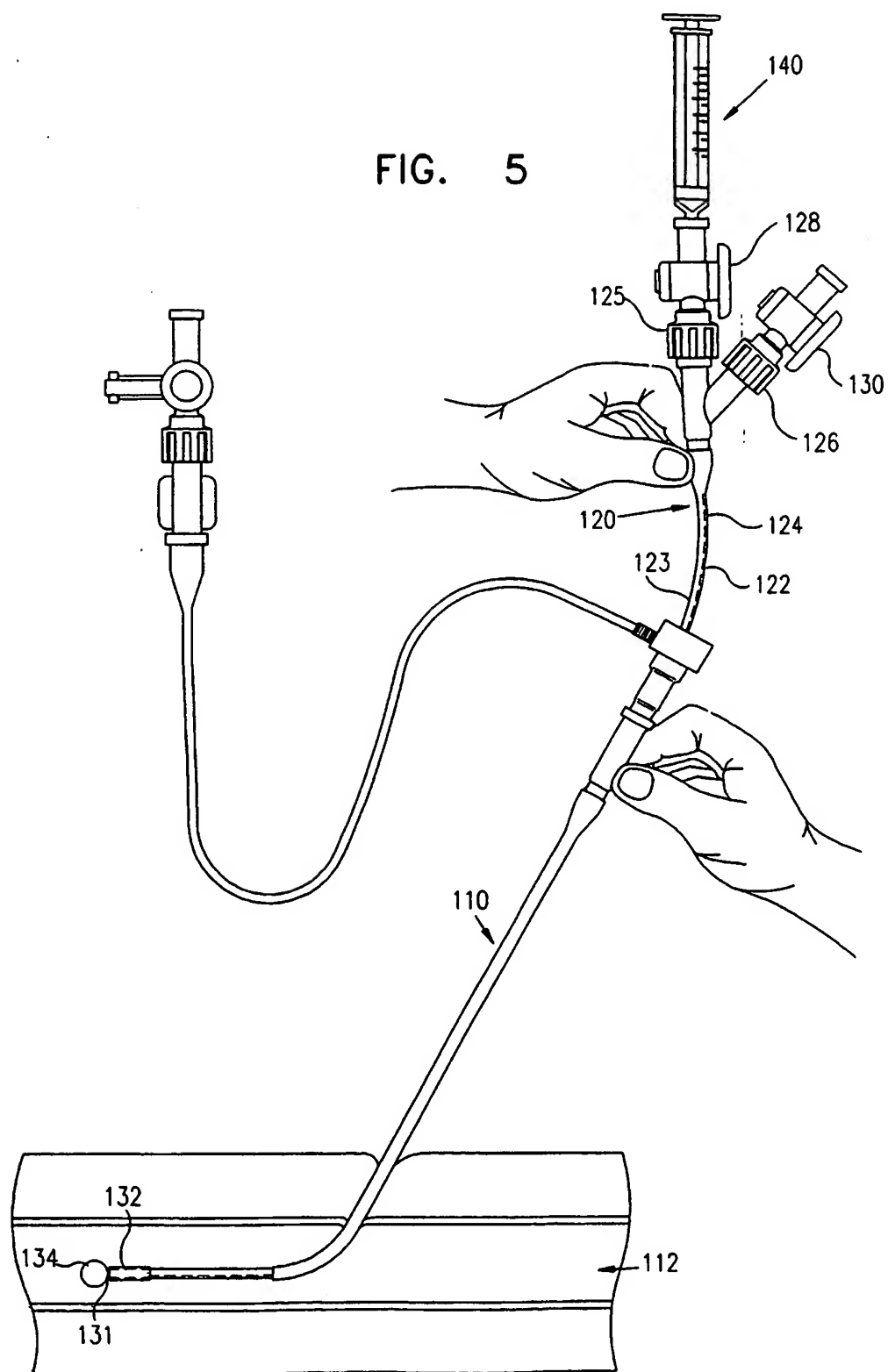


FIG. 6

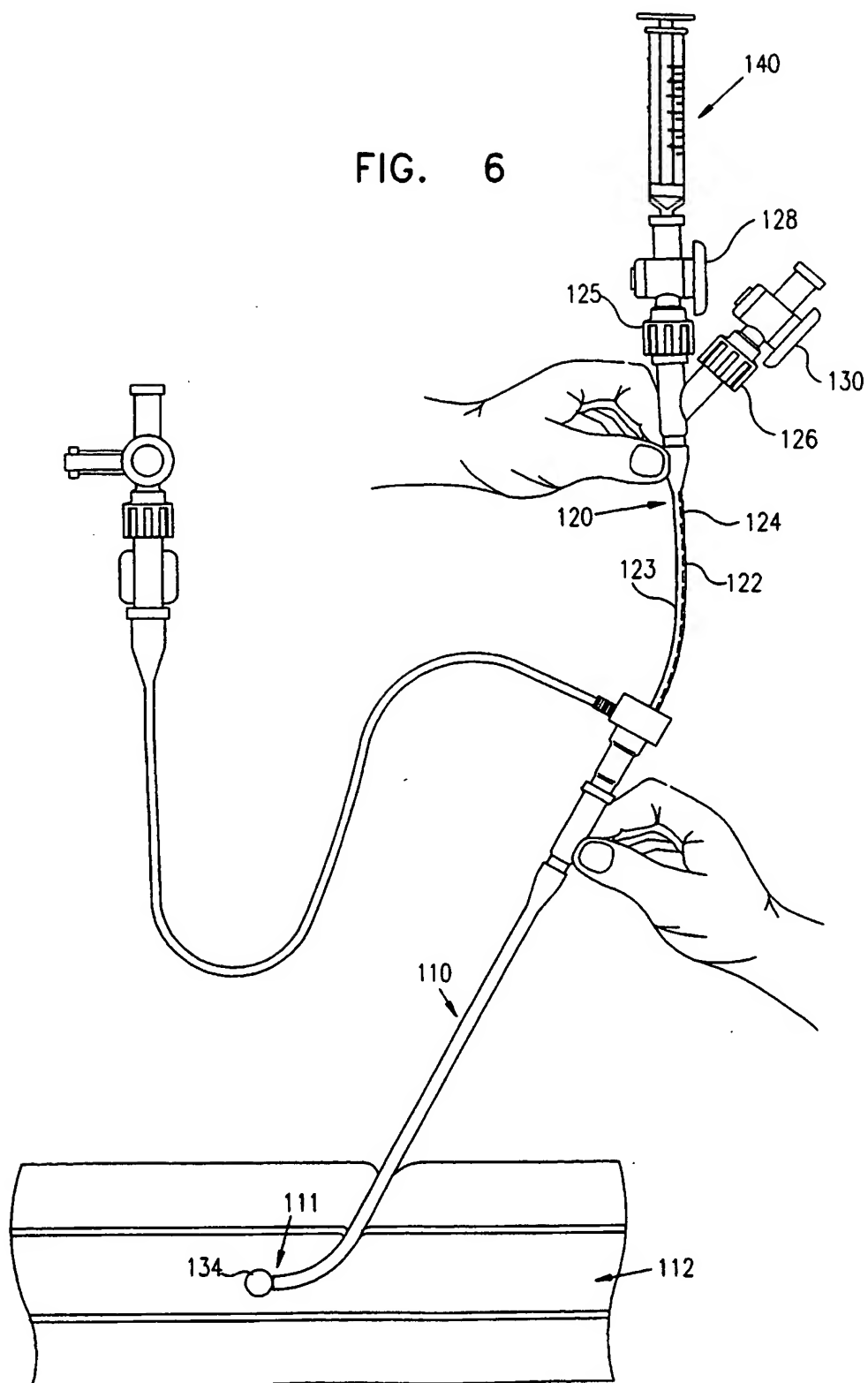


FIG. 7

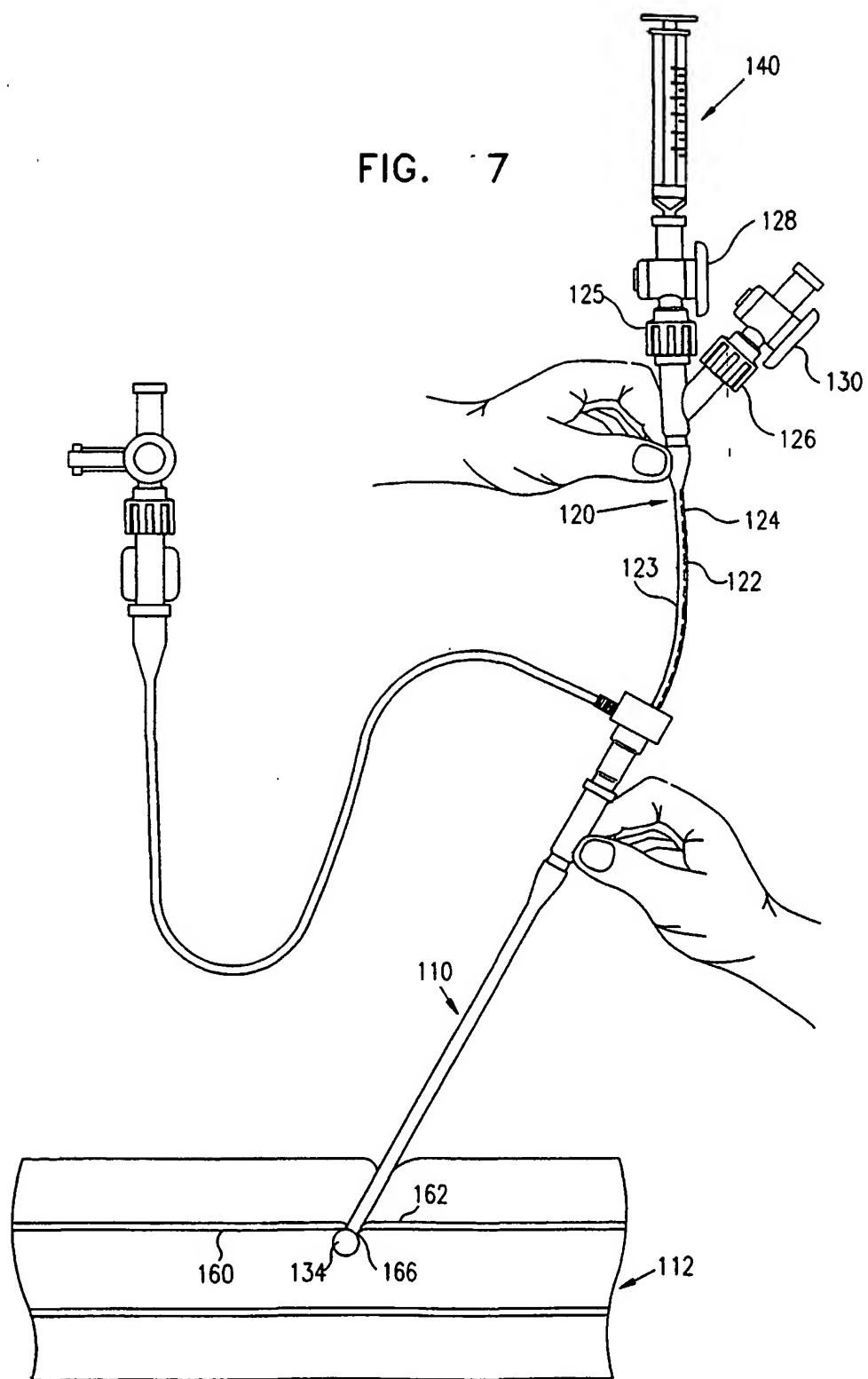


FIG. 8

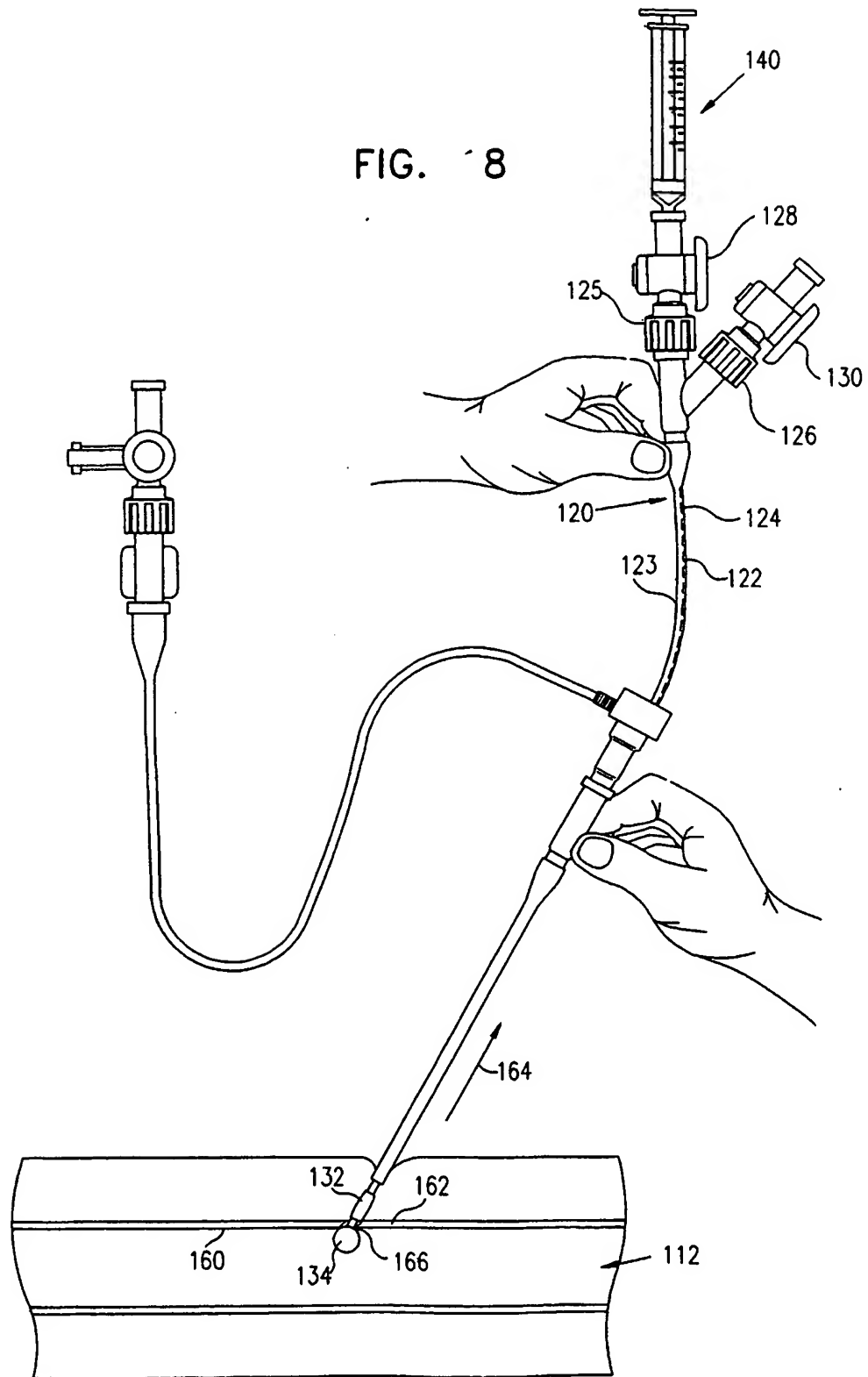


FIG. 9

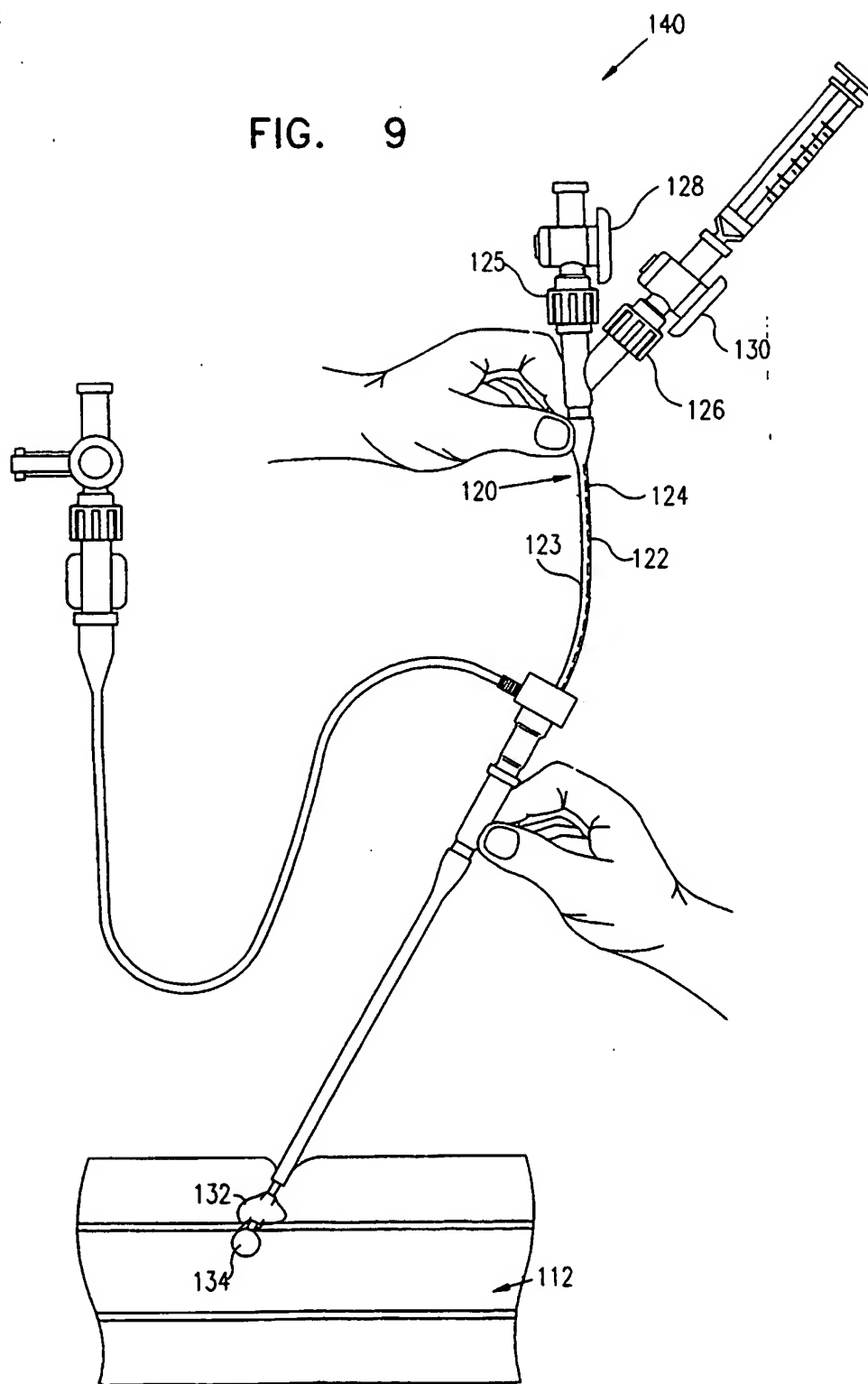


FIG. 10

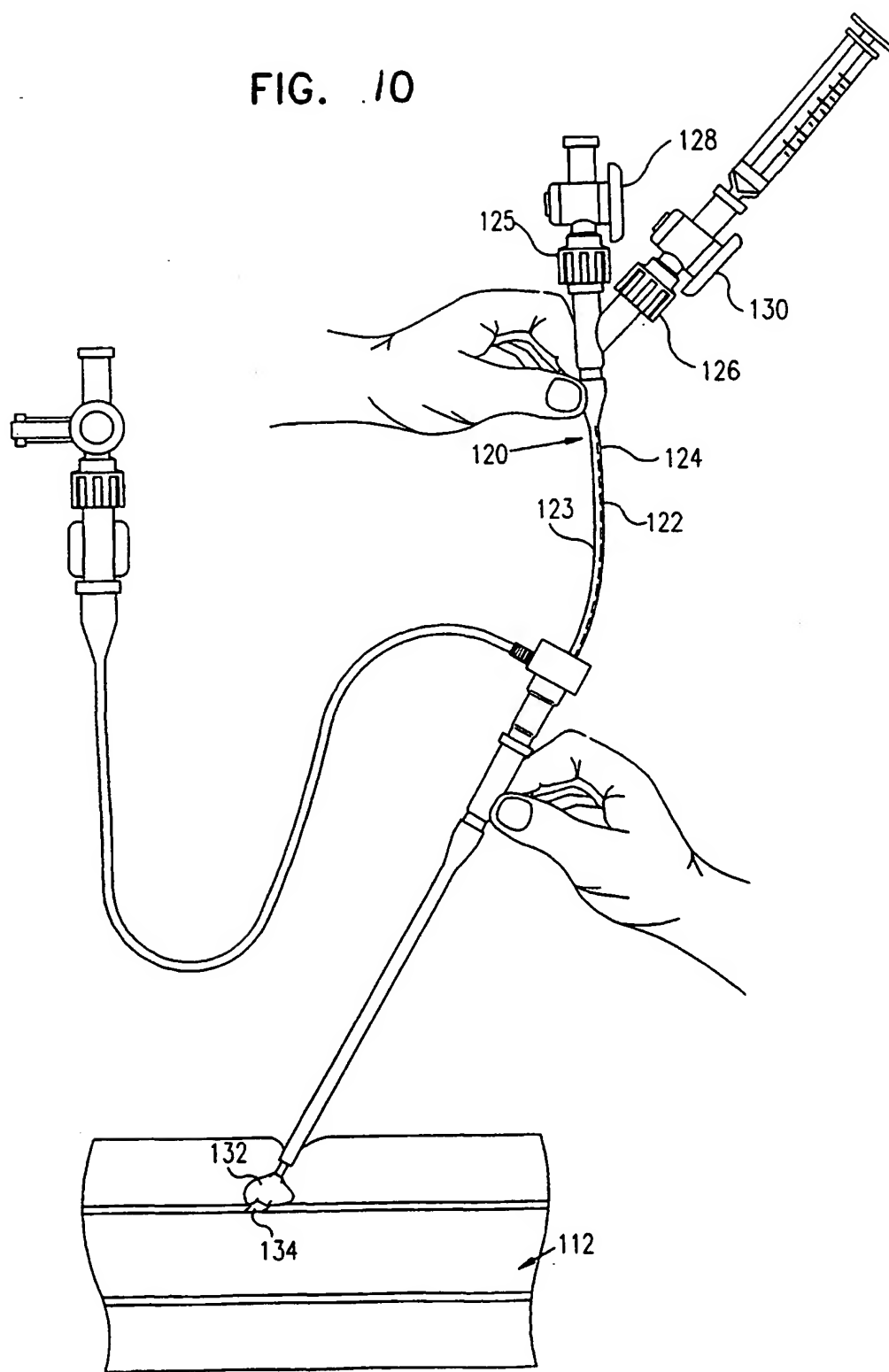


FIG. 11

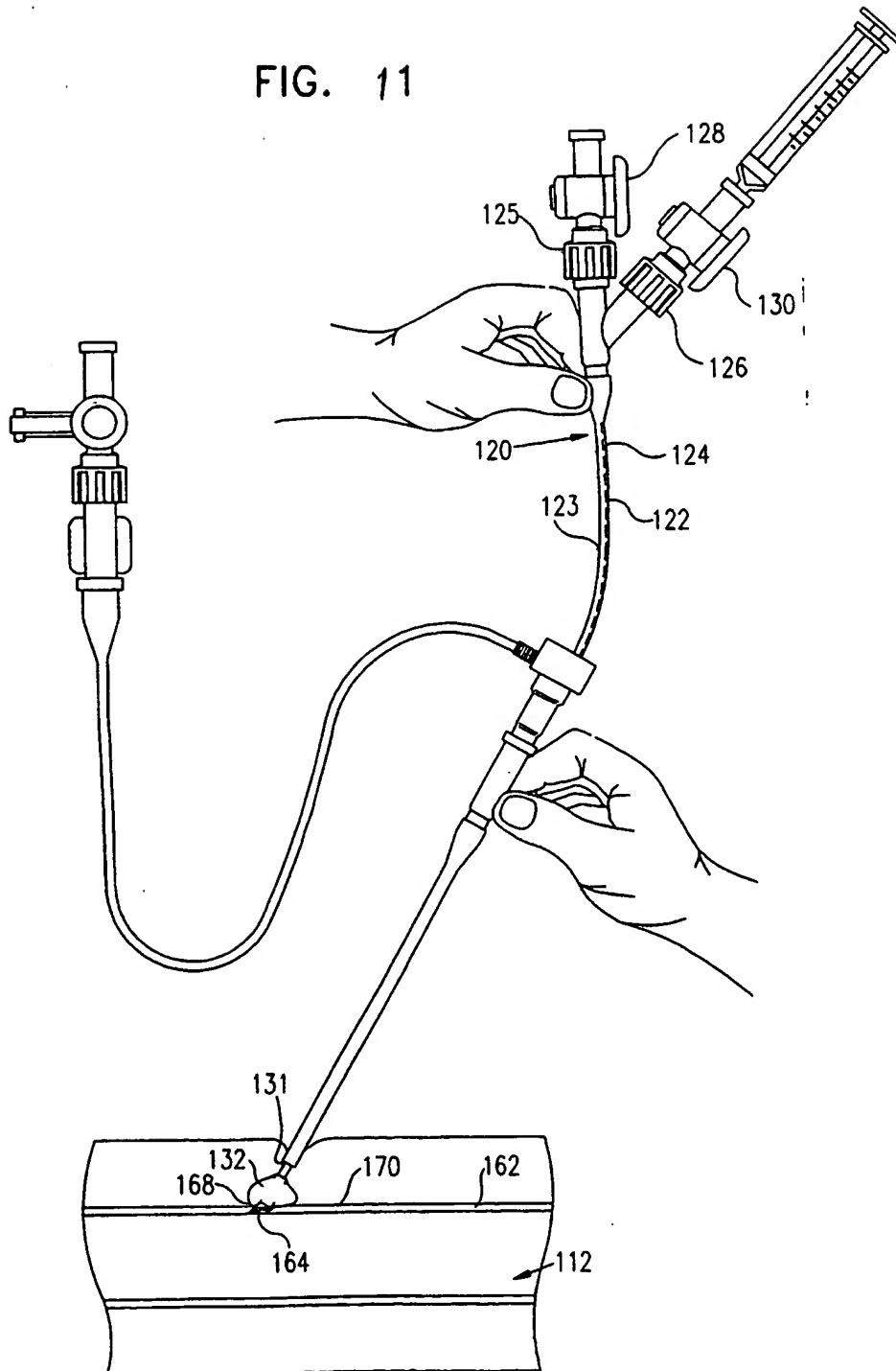


FIG. 12

